REMARKS

Claims 1, 3-7, 9, 10, 14-33, 35, 118 and 119 were rejected in an Office Action dated December 11, 2008. Claim 1 has been amended. Claims 27, 33, 35, 118 and 119 are now canceled. Support for the amendments may be found throughout the specification and particularly in the "Detailed Description of the Invention." Applicants respectfully request reconsideration of the present application in view of the following remarks.

Rejections under 35 U.S.C. §112, first and second paragraphs

All claims were rejected with regard to the amendment to the independent claims submitted previously (Applicants' paper of July 25, 2008) to the effect that the claim preamble was amended to read "A non-elastomeric article comprising..." The claims are currently amended to remove the non-elastomeric limitation.

Rejections under 35 U.S.C. §102

Claims 1, 5, 9, 10, 14, 17, 19, 20, 22-31, 33, 35 and 119 are rejected under 35 U.S.C. §102(b) as being anticipated by US Patent 5,061,276 to Tu et al. Of these, claims 27, 33, 35 and 119 are now canceled

Applicants note that the second line of Claim 1 is amended so that the word "essentially" now modifies "polytetrafluoroethylene" to render the meaning of the claim clearer. As such, the Examiner's comments regarding Tu et al. (at col. 3, lines 40-6) pertaining to "essentially porous" are now moot.

Applicants respectfully disagree with the rejection, particularly with regard to claim 1 (the sole remaining independent claim).

First, regarding "essentially polytetrafluoroethylene" as it pertains to the tube material and the covering film, the Examiner references Tu et al. at col. 3, lines 45-46, adding that "Tu discloses that the graft tube is made of polytetrafluoroethylene and has a covering of "essentially" polytetrafluoroethylene."

The Abstract of Tu et al. clearly states that it is describing "A vascular graft having a composite structure prepared by wrapping about the external surface of a tube having one or more layers of polytetrafluoroethylene or a polytetrafluoroethylene–elastomeric polymer blend, either alone or in combination, an elastic fiber, while maintaining the fiber under tension." As such, the presence of the elastic fibers is required. The graft of Tu et al. in all embodiments requires the presence of the elastomer in a quantity and/or form (i.e., with the elastomer blended with the PTFE) in an amount appropriate to affect the mechanical properties of the resulting tube, and/or provided with a coating of elastomer or a wrapping of elastomer fibers. The Examiner referenced Tu et al. at col. 3, lines 45-46. This portion of the Tu et al. specification, quoting the entire sentence (col. 3, lines 42-47) states that "According to a preferred embodiment of the invention a vascular graft is in the form of a composite structure prepared by *wrapping about the external surface of a tube* having one or more layers of polytetrafluoroethylene or polytetrafluoroethylene, either alone or in combination, *an elastic fiber...*" (Emphasis added.) While one can speculate as to why the word "polytetrafluoroethylene" was repeated (the Abstract appears to offer the correct intended language), it is clear that the elastic fiber is required for this embodiment. The portion of the Tu et al. specification referenced by the Examiner at col. 12, lines 19-21 states that "Fig. 2 shows an embodiment of the present invention having a luminal poly(tetrafluoroethylene) layer and poly(tetrafluoroethylene)/elastomer outer layer." (Emphasis added.) It is widely appreciated that PTFE is not an elastomer (note list of elastomers provided by Tu et al. at col. 3, lines 12-25 and conventional definition at col. 4, line 67 to col. 5, line 4). The present specification does not teach or suggest that an elastomer might be used in meaningful combination with the PTFE, hence the "essentially polytetrafluoroethylene" limitation of claim 1. (The words "elastic", "elastomer" and "elastomeric" do not appear in the present specification.) Tu et al. clearly do not anticipate these combined limitations.

Secondly, Applicants disagree with the Examiner's interpretation of Tu et al. at col. 10, lines 34-38 where he contend that the reference teaches that a 4mm tube can be diametrically expanded to 10mm. This portion of the Tu et al. specification states that "The inside diameter of the tubing, which is normally about 4mm to about 8mm, is radially expanded to be about 6mm to about 10mm." This clearly means that a 4mm inside diameter tube can be expanded to about 6mm, and an 8mm tube can be expanded to about 10mm (i.e., clearly much less than the 100% required by the present claims). See Tu et al. at col. 8, lines 43-47 that describes the same diametrical expansion: "The radial

expansion of the inside diameter of the tubing may increase from about 5% to about 50%, preferably about 10% to about 50%. For example, if the inside diameter of the inner layer is 4 mm, it may be increased to 6 mm." Tu et al. clearly do not teach diametrical expansion of 100%. Further, the described diametrical expansion of Tu et al., is a *manufacturing step* (step 6 of a nine step process). The present claim 1 (as amended herein), requires that the diametrical expansion is possible "in use", i.e., during implantation of the liner into a blood conduit.

The Examiner also states that "Tu also discloses the graft circumference increases as a result of the blood pressure, col. 5, lines 46-48." This passage states that "As blood flows through the graft the inherent elasticity provided by the fibers applied under tension *minimizes the dilatation of the graft.*" (Emphasis added.) This clearly is not describing a graft that is intended to increase substantially in diameter in response to internal pressure up to a predetermined, appreciably larger diameter. This description is typical of conventional vascular grafts which are intended to contain blood pressure for years of use while maintaining the fixed, nominal diameter at which they are sold for vascular replacements – an entirely different requirement than what is necessary for the diametrically expandable liner of the present invention.

Further, while Tu et al. do state that their graft has some degree of compliance in response to the alternating pressures resulting from systole/diastole, there is simply no suggestion that their tube, in response to increasing internal pressure, could increase in diameter up to a particular amount, after which it would resist further dilatation as required by the present claims. Their tube would be expected to simply continue to grow in diameter until failure by rupture occurred.

Finally, the Examiner states that "Because the same materials as claimed are disclosed by the prior art, the examiner asserts that the claimed physical properties are present in the prior art material to some extent even though they are not explicitly recited." Applicants disagree with the Office's assertion that the same materials are disclosed. Tu et al., as described in the above arguments, clearly always require the presence of the elastomer, either blended with the PTFE, used as a coating over a PTFE tube (which tube may also include blended elastomer), and/or elastic fibers wound about the outer surface of these PTFE or PTFE/elastomer blend tubes. The present application never suggests the use of elastomers, the tubes of the present invention being "essentially PTFE." As such, the physical properties of the present tubes and those of the Tu et al. tubes will clearly be different.

For all of these reasons, Tu et al. do not anticipate the present claims.

Rejections under 35 U.S.C. §103

Claims 6 and 7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tu et al. in view of Eilentropp (US 4,791,966, hereinafter "Eilentropp").

Tu et al. are discussed above. Eilentropp teaches the helical wrapping of a ribbon of PTFE about a cylindrical form (e.g., a wire or a removable mandrel) followed by fusion of the overlapping edges of the wrapped ribbon. The ribbon has a lens or trapezoidal cross section in order to minimize the thickness of the resulting tubular form.

The Examiner states that Tu et al. disclose layers of film applied to the tube are helical, but that they do not disclose that the PTFE layers are helical, referring to col. 11, lines 7-11 and col. 12, lines 1-4. These passages of the Tu et al. specification refer to winding elastic fibers (*not* film and not of PTFE). These fibers are wound so as to provide gaps or large pores between the adjacent windings (Tu et al. at col. 12, lines 1-6, see also Figure 8). The gaps between provide porosity to the resulting vascular graft.

The helically wound ribbon of Eilentropp is provided with overlapping adjacent edges. The ribbon is PTFE, but is never suggested to be porous PTFE and hence can be taken to result in a non-porous tube following fusion of the overlapping edges. The necessary porosity of the Tu et al. graft would be lost if the teachings of Eilentropp were combined, ruining the vascular graft of Tu et al. for its intended purpose. Further, one of skill in the art of making vascular grafts, in considering a teaching that requires helical wrapping of an elastic fiber with gaps between adjacent windings to make a porous graft with a degree of diametrical compliance, would not look to a teaching of an overlapping helical winding, would not look to an overlapping film in place of a fiber, would not look to inelastic PTFE to replace an elastic component, and finally would not look to a teaching that results in a non-porous tube and a noncompliant tube. There is simply no reason to combine these two references.

Further, all arguments above (pertaining to anticipation of claim 1 with regard to the Tu et al. reference) also apply to this rejection. For all of these reasons, this combination does not suggest the present invention.

Claims 18 and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tu et al. in view of Hughes et al. (US 4,728,328). Tu et al. are described above. Hughes et al. teach a cuffed tubular organic prosthesis. The Examiner notes that Hughes teaches an embodiment (Fig. 12) having three ends (a bifurcated graft). Applicants acknowledge this, but contend that these two references in combination do not suggest the present claimed invention for all of the reasons described above in the arguments pertaining to anticipation of claim 1 by the Tu et al. reference. It is noteworthy that neither reference suggests a diametrically expandable graft (to a limiting diameter) of essentially PTFE. The present reference is not suggested by this combination.

Claims 3, 4, 15, 16, and 21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tu et al. in view of Lee (US 5,123,917).

Tu et al. is described variously above. The Examiner notes that Tu et al. do not teach the possibility of a wall thickness of less than 0.1mm, and that Lee teaches the thickness of his graft is equal to about 0.1mm (col. 5, lines 56-59) and that Lee additionally teaches that a stent is used to secure his graft to a blood conduit (col. 5, lines 25-31).

Again, all of the arguments presented above pertaining to the anticipation of claim 1 by Tu et al. are applicable here. Further, the combination of Tu et al. with Lee will still require the elastomeric components of Tu et al. that are fundamental (particularly the elastic fibers). Applicants note that Tu et al. teach considerable quantities of these fibers are appropriate (300 helical passes in Example 3, 375 helical passes in Example 4). Clearly the presence of this extra material would add appreciable thickness to the PTFE/elastomer graft required by this combination. Further, the resulting graft would not be "essentially PTFE." This combination does not suggest the present invention.

Claim 118 is rejected under 35 U.S.C. §103(a) as being unpatentable over Goldfarb (US 6,436,135) in view of Eilentropp. Claim 118 is canceled at this time.

Conclusion

For the foregoing reasons, the present invention is neither taught nor suggested by any of the references of record. Accordingly, Applicants respectfully submit that these claims are now in form for allowance. If further questions remain, Applicants request that the Examiner telephone Applicants' undersigned representative before issuing a further Office Action.

Respectfully submitted,

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